

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
David Edwards, et al.

**Divisional of** Application No.: 09/835,302

Group Art Unit: Not Yet Assigned

Filed: February 5, 2004

Examiner: Not Yet Assigned

For: INHALATION DEVICE AND METHOD

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08a/b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO/SB/08a/b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
  - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
  - ☐ c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).

- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i).
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☒ 7. The Examiner's attention is directed to co-pending U.S. Patent Application Nos. 09/835,302, filed April 16, 2001 and 10/268,059, filed October 10, 2002, which is directed to related technical subject matter. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to that application now or upon issuance of these present applications as a

patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

- ☒ 8. Copies of the documents were cited by or submitted to the Office in Application No. 09/835,302, filed April 16, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a/b, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740, referencing Docket No. 000166.0109-US04.

Dated: February 5, 2004

Respectfully submitted,

By

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(202) 662-6000

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Divisional of 09/835,302
				Filing Date	February 5, 2004
				First Named Inventor	David Edwards
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	000166.0109-US04

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-3,635,219	01/1972	Altounyan et al.	
	AB	US-3,669,113	06/1972	Altounyan et al.	
	AC	US-3,795,244	03/1974	Lax et al.	
	AD	US-3,837,341	09/1974	Bell	
	AE	US-3,888,253	06/1975	Watt et al.	
	AF	US-3,906,950	09/1975	Cocozza	
	AG	US-4,013,075	03/1977	Cocozza	
	AH	US-4,069,819	01/1978	Valentini et al.	
	AI	US-4,105,027	08/1978	Lundquist	
	AJ	US-4,192,309	03/1980	Poulsen	
	AK	US-4,240,418	12/1980	Roskamp et al.	
	AL	US-4,860,740	08/1989	Kirk et al.	
	AM	US-4,889,114	12/1989	Kladders	
	AN	US-4,995,285	02/1991	Valentini et al.	
	AO	US-5,152,284	10/1992	Valentini et al.	
	AP	US-5,239,992	08/1993	Bougamont et al.	
	AQ	US-5,301,666	04/1994	Lerk et al.	
	AR	US-5,349,947	09/1994	Newhouse et al.	
	AS	US-5,524,613	06/1996	Haber et al.	
	AT	US-5,595,175	01/1997	Malcher et al.	
	AU	US-5,647,349	07/1997	Ohki et al.	
	AV	US-5,651,359	07/1997	Bougamont et al.	
	AW	US-5,673,686	10/1997	Villax et al.	
	AX	US-5,685,294	11/1997	Gupte et al.	
	AY	US-5,727,546	03/1998	Clarke et al.	
	AZ	US-5,740,794	04/1998	Smith et al.	
	AA1	US-5,785,049	07/1998	Smith et al.	
	AB1	US-5,797,391	08/1998	Cook et al.	
	AC1	US-5,810,004	09/1998	Ohki et al.	
	AD1	US-5,860,419	01/1999	Davies et al.	
	AE1	US-5,896,855	04/1999	Hobbs et al.	
	AF1	US-5,921,237	07/1999	Eisele et al.	
	AG1	US-6,092,522	07/2000	Calvert et al.	
	AH1	US-6,102,035	08/2000	Asking et al.	
	AI1	US-6,116,237	09/2000	Schultz et al.	
	AJ1	US-6,116,238	09/2000	Jackson et al.	
	AK1	US-6,142,145	11/2000	Dagsland et al.	
	AL1	US-US 2003/0094173-A1	05-22-2003	Burr et al.	

Examiner Signature		Date Considered	
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
	BA	WO-WO 94/08552-A2	04-28-1994	Mecikalski et al.		
	BB	WF-WO 00/64519-A1	11-02-2000	Haikarainen et al.		
	BC	WO-WO 01/07107	02/2001	Pharmaceutical Discovery Corporation		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Bisgaard, H. et al., Fine particle mass from the Diskus inhaler and Turbuhaler inhaler in children with asthma, European Respiratory Journal, 11: 1111-1115, May 1998.		
	CB	de BOER, A.H. et al., "Inhalation characteristics and their effects on in vitro drug delivery from dry powder inhalers, Part 1. Inhalation characteristics, work of breathing and volunteers' preference in dependence of the inhaler resistance," International Journal of Pharmaceutics 130: 231-244 (1996).		
	CC	Dunbar, Craig A. et al., A Comparison of Dry Powder Inhaler Dose Delivery Characteristics Using a Power Criterion, PDA Journal of Pharmaceutical Science & Technology, 54(6): 4780484, November/December 2000.		
	CD	Feddah, Majid R. et al., In-Vitro Characterisation of Metered Dose Inhaler Versus Dry Powder Inhaler Glucocorticoid Products: Influence of Inspiratory Flow Rates, J. Pharm. Pharmaceut. Sci. ( <a href="http://www.ualberta.ca/~csp">www.ualberta.ca/~csp</a> ) 3(3): 317-324 (2000).		
	CE	Koskela, T. et al., Efficacy of salbutamol via Easyhaler® unaffected by low inspiratory flow, Respiratory Medicine 94: 1229-1233 (December 2000).		
	CF	Nielsen, K.G. et al., Flow-dependent effect of formoterol dry-powder inhaled from the Aerolizer®, European Respiratory Journal, 10: 2105-2109 (September 1997).		
	CG	Richards, Robert and Saunders, Michael, Need for a comparative performance standard for dry powder inhalers, Thorax 48: 1186-1187 (November 1993).		
	CH	Ross, Danna L. and Schultz, Robert K., Effect of Inhalation Flow Rate on the Dosing Characteristics of Dry Powder Inhaler (DPI) and Metered Dose Inhaler (MDI) Products, Journal of Aerosol Medicine, 9: 215-226 (November 2, 1996).		
	CI	Smith, Karen J. et al., Influence of Flow Rate on Aerosole Particle Size Distributions from Pressurized and Breath-Actuated Inhalers, Journal of Aerosol Medicine, 11: 231-245 (November 4, 1998).		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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